



hhc
human health care

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Eisai Inc. Supports Acting Surgeon General's Call to Action to Prevent Deep Vein Thrombosis and Pulmonary Embolism

*Support Reflects Eisai's human health care (hhc) Mission
to Serve the Needs of Patients and Families*

WOODCLIFF LAKE, NJ – SEPTEMBER 15, 2008 — Eisai Inc. announced today its support of the Acting Surgeon General's Call to Action on venous thromboembolism (VTE), a serious and potentially life-threatening condition that includes deep vein thrombosis (DVT) and pulmonary embolism (PE). The Call to Action urges all Americans to learn about and prevent these treatable conditions.

The announcement was made today during the annual meeting of the Venous Disease Coalition (VDC), an alliance of more than 30 leading health professional societies and patient advocacy groups devoted to the prevention, early detection and prompt treatment of venous disease and its complications.

“Hundreds of thousands of Americans develop deep vein thrombosis and pulmonary embolism each year, underscoring the need for greater awareness of VTE,” said Cynthia Schwalm, President, Eisai Inc. “We are pleased to support the Acting Surgeon General's recommendations calling for increased awareness of DVT and PE, evidence-based practices for DVT and more research on the causes, prevention and treatment of DVT.”

Eisai Inc. markets FRAGMIN[®] (dalteparin sodium injection), approved by the U.S. Food and Drug Administration (FDA) for prevention of DVT, which may lead to PE, in patients undergoing hip replacement surgery, in at-risk patients undergoing abdominal surgery and in at-risk acutely ill patients whose mobility is severely restricted. FRAGMIN[®] is also approved for prophylaxis of ischemic complications resulting from unstable angina and non-Q-wave myocardial infarction (heart attack), when used with aspirin.

In addition, FRAGMIN[®] is the only low molecular weight heparin (LMWH) approved in the United States for the extended treatment of symptomatic VTE (proximal DVT and/or PE) to reduce the recurrence of VTE in patients with cancer.

VTE is a frequent medical complication for patients with cancer, occurring in 4 to 20 percent of cases. Patients with cancer have an increased risk of VTE compared to those without cancer. Additionally, patients with cancer may be immobilized, which predisposes the patient to this condition.

Important Safety Information

SPINAL/EPIDURAL HEMATOMAS

When neuraxial anesthesia (epidural/spinal anesthesia) or spinal puncture is employed, patients anticoagulated or scheduled to be anticoagulated with low molecular weight heparins or heparinoids for prevention of thromboembolic complications are at risk of developing an epidural or spinal hematoma which can result in long-term or permanent paralysis.

The risk of these events is increased by the use of indwelling epidural catheters for administration of analgesia or by the concomitant use of drugs affecting hemostasis such as non steroidal anti-inflammatory drugs (NSAIDs), platelet inhibitors, or other anticoagulants. The risk also appears to be increased by traumatic or repeated epidural or spinal puncture.

Patients should be frequently monitored for signs and symptoms of neurological impairment. If neurological compromise is noted, urgent treatment is necessary.

The physician should consider the potential benefit versus risk before neuraxial intervention in patients anticoagulated or to be anticoagulated for thromboprophylaxis (also see WARNINGS, Hemorrhage and PRECAUTIONS, Drug Interactions in full prescribing information).

FRAGMIN[®] is contraindicated in patients with active major bleeding or with known hypersensitivity to the drug, heparin, or pork products, or with thrombocytopenia associated with a positive anti-platelet antibody test.

Patients undergoing regional anesthesia should not receive FRAGMIN[®] for unstable angina or non-Q-wave myocardial infarction, and patients with cancer undergoing regional anesthesia should not receive FRAGMIN[®] for extended treatment of symptomatic VTE, due to an increased risk of bleeding associated with the dosage of FRAGMIN[®] recommended for these indications.

FRAGMIN[®] Injection is not intended for intramuscular administration.

FRAGMIN[®] cannot be used interchangeably (unit for unit) with unfractionated heparin or other low-molecular-weight heparins.

FRAGMIN[®], like other anticoagulants, should be used with extreme caution in patients who have an increased risk of hemorrhage; bleeding can occur at any site during therapy. An unexpected drop in hematocrit or blood pressure should lead to a search for a bleeding site.

FRAGMIN[®] should be used with extreme caution in patients with history of heparin-induced thrombocytopenia.

In FRAGMIN[®] clinical trials supporting non-cancer indications, platelet counts of $<100,000/\text{mm}^3$ and $<50,000/\text{mm}^3$ occurred in $<1\%$ and $<1\%$, respectively.

In a clinical trial of patients with cancer and acute symptomatic VTE treated for up to 6 months in the FRAGMIN[®] treatment arm, platelet counts of $<100,000/\text{mm}^3$ occurred in 13.6% of

patients, including 6.5% who also had platelet counts less than 50,000/mm³. In the same clinical trial, thrombocytopenia was reported as an adverse event in 10.9% of patients in the FRAGMIN[®] arm and 8.1% of patients in the oral anticoagulant arm. FRAGMIN[®] dose was decreased or interrupted in patients whose platelet counts fell below 100,000/mm³.

Thrombocytopenia of any degree should be monitored closely. Heparin-induced thrombocytopenia can occur with administration of FRAGMIN[®]. The incidence of this complication is unknown at present. In clinical practice, rare cases of thrombocytopenia with thrombosis have also been observed.

FRAGMIN[®] should be used in caution in patients with bleeding diathesis, thrombocytopenia or platelet defects; severe liver or kidney insufficiency, hypertensive or diabetic retinopathy, and recent gastrointestinal bleeding.

Each multiple-dose vial of FRAGMIN[®] contains benzyl alcohol as a preservative [which] has been reported to be associated with a fatal “Gaspings Syndrome” in premature infants. Because benzyl alcohol may cross the placenta, FRAGMIN[®] preserved with benzyl alcohol should be used with caution in pregnant women and only if clearly needed. If anticoagulation with FRAGMIN[®] is needed during pregnancy, preservative-free formulations should be used, where possible.

FRAGMIN[®] should be used with care in patients receiving oral anticoagulants, platelet inhibitors, and thrombolytic agents because of increased risk of bleeding (see **PRECAUTIONS, Laboratory Tests**). Aspirin, unless contraindicated, is recommended in patients treated for unstable angina or non-Q wave myocardial infarction (see **DOSAGE AND ADMINISTRATION** in full prescribing information).

Allergic reactions (i.e., pruritus, rash, fever, injection site reaction, bulleous eruption) have occurred rarely. A few cases of anaphylactoid reaction have been reported.

The most commonly reported side effect is hematoma at the injection site.

Please see www.FRAGMIN.com for full prescribing information.

About Eisai Inc.

Eisai Inc. is a U.S. pharmaceutical subsidiary of Eisai Co., Ltd., a research-based *human health care (hhc)* company that discovers, develops and markets products throughout the world. Eisai focuses its efforts in three therapeutic areas: neurology, gastrointestinal disorders and oncology/critical care. Established in 1995 and ranked among the top-20 U.S. pharmaceutical companies (based on retail sales), Eisai Inc. began marketing its first product in the United States in 1997 and has rapidly grown to become an integrated pharmaceutical business with fiscal year 2007 (year ended March 31, 2008) sales of approximately \$3 billion, including the results of the acquisition of MGI PHARMA, Inc.

Eisai Inc. employs approximately 1,800 people at its headquarters in Woodcliff Lake, NJ, at its state-of-the-art pharmaceutical production and formulation research and development facility in Research Triangle Park, NC, and in the field. For more information about Eisai, please visit www.eisai.com.